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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,639	05/16/2001	Nissim Darvish	20066.73	3851
54042	7590	10/19/2005	EXAMINER	
WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP			EVANISKO, GEORGE ROBERT	
250 PARK AVENUE			ART UNIT	
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DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 09/720,639	Applicant(s) DARVISH ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,7,10-15,55,56,59-64,151-177,205 and 206 is/are pending in the application.
- 4a) Of the above claim(s) 152-154,156-160,165 and 169-171 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6,7,55 and 56 is/are allowed.
- 6) ☒ Claim(s) 10-15,59-64,151,155,161-164,166-168,172-177,205 and 206 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 152-154, 156-160, 165, 169-171 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/13/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205 and 206 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not disclosed is the extended pacing signal having an overall duration greater than “8 ms” from “a time of initiation of application of that portion of the signal that initiates action potential propagation”, in combination with the other steps/elements in the claims. Although the specification may state that only a small, initial fraction of signal 60 is needed for actually pacing the heart and the remainder of the energy in the signal is applied to increase the contractility, the claims do not state this (such as “having an overall duration greater than 8 ms, wherein a small initial fraction of the signal is needed for actually pacing the heart”). This small, initial fraction

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was originally part of the “overall duration greater than 8 ms” and not before the duration of 8 ms and therefore saying that the overall duration is greater than 8 ms “from a time of initiation...propagation” is considered a new limitation/range. As stated in the arguments and on page 17 of the specification, the amount of time of this small initial fraction is approximately 1-2 ms and this amount is part of the duration of 8 ms (or should be subtracted from the originally presented “greater than 8 ms”). This rejection is related to new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al (5978703).

Kroll applies a signal that is capable of meeting the intended use recitations of pacing the heart and inherently performs a method for pacing (claim 50), modifying a characteristic of pulsatile blood flow (claim 151), and increasing a contractility by 10% (claim 155), because he provides a signal (10-200 Volts [column 5, lines 10-19], 1-5 ms pulse width [figure 4], in a train of 10 pulses with 500 ms between pulses [figure 4, column 4, and/or column 5, line 59]) that will/can cause an action potential of the heart, therefore the signal will “pace” the heart. It is noted that the “overall duration” of the pulse train is greater than 8 ms since 10 pulses at 5 ms is equal to 50 ms. Also, Kroll discloses the use of sensors, 44 or 46, 406, for determining when to

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apply/modify the signal for the heart for enhancement, such as during arrhythmias (column 5, line 63 and column 6, lines 10-19). In addition, since his signal and electrodes will be used for increasing pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, and 177 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower (6141586).

Mower applies a signal that is used for pacing the heart and performs a method for pacing, and inherently modifies a characteristic of pulsatile blood flow (claim 151), and increases a contractility by 10% (claim 155), because he provides a signal (8 ms anodal and 0.3-

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1.5 ms cathodal [column 5, lines 10-19 and column 8] or over 200 ms post heartbeat [column 5, line 5 and throughout] and 20 Volts) that will cause an action potential of the heart and is of the same or similar pulse duration and characteristic as the applicant's pulse. Also, Mower discloses the use of sensors, column 7, lines 20-35, for determining when to apply/modify the signal for the heart for enhancement. In addition, since his signal and electrodes will be used for increasing cardiac contraction and pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass. For claim 162, the signals will be applied "according to a predetermined time sequence" since the signals were programmed to be delivered "cyclically paced either on the same or similar time protocol or independently" (column 7, line 67). In addition, Mower calls his signal (including the anodal portion) a pacing or stimulation signal and therefore provides a pacing signal greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation. Although Mower says that the anodal portion could be subthreshold, this occurs in an "alternative embodiment" (column 8, line 41). Finally, for claims 205 and 206, it is noted that the biphasic signal of figures 4-6 is a single pulse (one pulse with two phases).

In the alternative, Mower does not disclose the pacing signal is greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation and that the pulse is a single pulse. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the biphasic cardiac pacing signal as taught by Mower with the pacing signal being greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation and the pulse being a single pulse, because Applicant has not disclosed that the pacing signal being greater than 8 ms from a time of initiation of

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application of the signal that initiates action potential propagation or the pulse being a single pulse provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the biphasic pulse being greater than 8 ms from the beginning of the pulse as taught by Mower, because the pulse does not leave a net charge on the electrodes and improves contraction while damage to the tissue adjacent to the electrode is diminished.

Therefore, it would have been an obvious matter of design choice to modify Mower to obtain the invention as specified in the claim(s).

Claim 167 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll et al. Kroll states that he uses his system in a pacemaker, shows in column 5 that pacemakers use lower energy pulses than his extended signals, and only provides his extended signal for responsive to a demand for enhancement and therefore will apply the pacing signal in the absence of the demand.

In the alternative, Kroll discloses the claimed invention except for applying a lower energy pacing signal in the absence of the enhancement signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using the extended signal pacemaker as taught by Kroll, with a pacing signal in the absence of the enhancement signal since it was known in the art that pacemakers apply a low energy pacing signal (lower than the energy of Kroll's extended signal) and in the absence of an enhancement signal related to pressure or fibrillation, asystole, tachycardia, etc to provide a low energy signal that can pace the heart over a longer period for bradycardia.

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Claims 163 and 167 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower. Mower teaches the use of his ventricular extended pacing signal in an atrial pacemaker (column 9) and inherently will be of a smaller duration and lower energy and not rely on the ventricular enhancement signal since regular pacing signals are of a shorter duration, lower energy, and are applied based on atrial needs.

Mower discloses the claimed invention except for the conveying a pacing signal having a shorter duration to a different chamber (claim 163) and in the absence of enhancement, conveying a signal with a lower energy (claim 167). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using an atrial and ventricular pacemaker as taught by Mower, with conveying a pacing signal having a shorter duration to a the atrial chamber and in the absence of enhancement, conveying a signal with a lower energy since it was known in the art that atrial pacemakers use a pacing signal applied in the atrium having a shorter duration than 8 seconds to provide a pacing signal of low energy to pace the atrium and to apply with signal in the absence of the enhancement signals used in Mower to provide bradycardia support pacing to the atrium when needed.

Claim 174 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll or Mower.

Kroll or Mower discloses the claimed invention except for the sensing being a monophasic action potential signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensing and stimulation system as taught by Kroll or Mower, with the sensing being a monophasic action potential signal since it was

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known in the art that sensing and stimulation systems sense a monophasic action potential signal to determine which portions of the heart are viable.

Claims 205 and 206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al.

Kroll discloses the claim invention but does not disclose the pacing signal being a single pulse. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cardiac pacing train signal as taught by Kroll with the pacing signal being a single pulse, because Applicant has not disclosed that the pacing signal being a single pulse provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the extended pacing train signal being greater than 8 ms as taught by Kroll, because the pulse train provides contraction of the heart to force hemodynamic output during times of need.

Therefore, it would have been an obvious matter of design choice to modify Kroll to obtain the invention as specified in the claim(s).

Allowable Subject Matter

Claims 6, 7, 55, and 56 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. In addition, the argument that Kroll does not provide a "pulse duration" greater than 8 ms is not persuasive. The claims state that the "overall duration" of the pacing signal is greater than 8 ms and that the pacing

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signal is a train of pulses and not that the “pulse duration” is greater than 8 ms. Also, as can be seen by original claim 11, the pulses have a “pulse duration” of at least 1 ms. Since Kroll provides 5 ms pulses in a train of 10 pulses, Kroll therefore provides a pacing signal of 50 ms, which meets the applicant’s claimed limitation of greater than 8 ms. It is noted that the applicant also provides a dead/off time between pulses, as seen in the applicant’s specification on page 16, figure 9, etc.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

10/16/05

GRE
October 16, 2005